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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,451	12/12/2003	Randall Fuerst		2007

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CONN. ANALYTICAL CORP.  
Att: Joseph J. Bango, Jr.  
696 AMITY ROAD  
BETHANY, CT 06524

EXAMINER

VARGOT, MATHIEU D

ART UNIT	PAPER NUMBER
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1791

MAIL DATE	DELIVERY MODE
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02/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/735,451

Applicant(s)

FUERST ET AL.

Examiner

Mathieu D. Vargot

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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1. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although it may be a minor matter, it would appear that the diameter being disclosed as "ranging down to tens of nanometers or less" is in fact the diameter of the mat being produced, not the diameter of the fibrils themselves. See the last sentence of paragraph 0026 of the instant PGPub. The point is, applicant should properly amend the claims in a manner consistent with what is taught in the specification, and not use language set forth therein in whatever manner deemed desirable. Hence, the instant independent claims and claim 10 are submitted to contain new matter based on this. The language should be changed to what is disclosed in the specification concerning the diameter of the fibrils and the diameter of the mat produced therefrom. More importantly, instant claims 11 and 12 are submitted to still contain language clearly not supported in the specification as filed. The term "hydrogel" is mentioned in the background of the prior art section (paragraph 0005 of instant PG Pub) and the term "Hema" is taught in paragraph 0026 as being suitable for the instant process. However, there is no indication that the Hema would be combined with collagen or that a silicone hydrogel or combinations of polymers were contemplated. At best applicant can claim —collagen or HEMA—as the polymers, and not combinations of these. Since hydrogel was mentioned in the background, it would be new matter to include it with the polymers used. Certainly, a "silicone hydrogel"

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would be new matter. Also, despite applicant's comments to the contrary, instant claim 12 is simply not supported in the specification as filed. There is no disclosure of the region of the target "characterized to form a predetermined prescriptive or refractive surface".

.2.The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al (see paragraphs 0147, 0204, 0208 for a disclosure of making a corneal tissue; paragraphs 0010-0012, 0073, 0087, 0126-0127, 0155, 0160, 0178 and 0306 and Figure 3 for the basic electrospinning process) in view of Noakes et al 5,222,663, either alone, or further in view of Burgess et al (see claim 36 therein).

Simpson et al and Burgess et al are applied for reasons of record, with Simpson et al clearly envisioning the formation of corneal tissue that would have to be transparent to be useful, these references failing to teach the aspect of alternating the output voltage.

Noakes et al -663 teaches providing an alternating potential or voltage in an electrostatic spray deposition (see col. 1, lines 11-15), the advantage being the avoidance of charge build-up on the target (see Abstract, last line and column 5, lines 5-20). Given the microprocessor control over the potential in Simpson et al (see paragraph 0128), it is submitted prime facie obvious that one of ordinary skill in the art

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would have modified the process disclosed therein as taught by Noakes et al –663 to prevent charge build-up on the target and fibers deposited there. It is respectfully submitted that the additionally claimed limitations would have been obvious from Simpson et al. Indeed, Simpson et al discloses a voltage of up to 30,000 volts, employing a polymer in a suitable solvent, the instant conductive target and needle, formation of a Taylor cone during the electrospinning, and moving the tip (paragraph 0010) and layering (paragraph 0087) to form the desired biomedical device. The diameter of the fibrils is disclosed as being from microns to less than 100 nm (see paragraph 0116) and paragraph 0145 details how the branching and formation of fibers can be controlled through processing conditions—voltage applied, target geometry, distance of needle to target and diameter of the needle. Applying the fibers over an area that is larger than the final article desired would clearly have been obvious in Simpson et al to ensure that the desired article is made and the surrounding portions can be cut away. This is fairly conventional in the art and is submitted to have been within the skill level of the shaping taught in paragraph 0011 of Simpson et al. Also, keep in mind that Simpson et al clearly discloses that the article made would be a cornea or tissue for a cornea. In that the cornea is the **transparent** portion of the external covering of the eyeball lying over the iris and pupil and permits **light to enter the interior of the eye**, it is rather clear that Simpson et al must have envisioned making the article transparent. Making a contact lens in lieu of a corneal tissue or corneal implant would have been obvious to one of ordinary skill in the art. At any rate, Burgess et al shows the

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equivalence of compositions and methods for making in vivo tissues/implants and extra corporeal items such as contact lenses—see claim 36 therein.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/414,796 in view of Burgess (claim 36). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application –796 and the instant set forth substantially similar inventions, the main difference being that the claims in –796 call for the production of corneal tissue and those of the instant application the formation of a contact lens. One of ordinary skill in this art knows that corneal implants/tissues and a contact lens which would fit over the cornea would be made of similar, optically

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transparent materials and would be made by similar methods. Burgess shows that biomedical devices would include in vivo as well as extra corporeal devices. It would have been obvious to have utilized the process set forth in claims 1-11 of copending application –796 to make a contact lens as taught by Burgess--Burgess teaches the equivalency of in vivo tissues/implants and contact lenses-- dependent on the exact optical article desired. Any additional differences in the claims would have been within the skill level of the art. For instance, depositing material over a surface area larger than that required to make the article and then cutting the excess would have been an obvious modification to the claims of copending application –796 to ensure that the final article edges are fashioned as necessary.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-16 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/414,796 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. Claims 1-16 are rejected over copending application –796 essentially for reasons set forth in paragraph 3, supra.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or

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by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In view of the amendment, new art has been applied which renders the instant claims as obvious. A new matter rejection still exists as set forth in paragraph 1, supra. The declaration by Dr. Gary Wnek is noted but is not persuasive. First of all, it is noted that the declaration was apparently intended for the companion case, 10/414,796, although it would also have relevance to the instant application. However, since Simpson et al discloses corneal tissue production, it is submitted that such tissue would have some degree of optical transparency, or otherwise it would fail in its intended purpose. It is recognized that Simpson et al didn't contemplate using a varying potential—that is why Noakes et al –663 is being applied. At any rate, the rejection is based on a 103 that would have validity even if the primary reference to Simpson et al never “directly contemplated” a clear mat. Again, one wonders how corneal tissue would be contemplated in Simpson et al if such tissue were not to be optically transparent to some degree. While the process of Simpson et al may indeed be used for in vivo scaffolding use, and the instant claims call for making a contact lens, such is not seen to obviate the rejection. Indeed, one of ordinary skill in this art realizes that compositions



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and methods used to make implants—in vivo tissues—are also used to make extra corporeal devices such as contact lenses. See claim 36 of Burgess et al.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mathieu D. Vargot whose telephone number is 571 272-1211. The examiner can normally be reached on Mon-Fri from 9 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson, can be reached on 571 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Vargot  
February 3, 2008

  
Mathieu D. Vargot  
Primary Examiner  
Art Unit 1791

2/3/08